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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,202	12/27/2001	Frans Eduard Janssens	JANS-0027	9001

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EXAMINER

HABTE, KAH SAY

ART UNIT	PAPER NUMBER
1624	//

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/030,202	JANSSENS ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Kahsay Habte, Ph. D.	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 May 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,16,17 and 22 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4,6,8-15 and 18-21 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |                                                                                                              |                                                                              |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

## DETAILED ACTION

1. Claims 1-22 are pending.

### ***Election/Restriction***

2. Applicant's election with traverse of Group V, Claims 1-2 (in part), 3, 4, 6, 8-15 (in part) and 18-21 (in part) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the groups of inventions are related to a single general inventive concept, and thus the lack of unity is improper. The examiner disagrees with applicants. The technical features of Groups I-VIII differ one from the other. For example, the special technical feature of benzimidazoles {-a<sup>1</sup>=a<sup>2</sup>-a<sup>3</sup>=a<sup>4</sup>- is (a-1)} is different from the special technical features of monoazines fused to imidazoles {-a<sup>1</sup>=a<sup>2</sup>-a<sup>3</sup>=a<sup>4</sup>- is (a-2), (a-3), (a-4 or (a-5)}. There is no common special technical feature among said inventions. The special technical feature of substituent Q attached to benzimidazoles or Q attached to monoazines fused to imidazoles are also different one from the other. Note that Q also has special technical features, thus, azepine attached to benzimidazoles is different than azepine attached to monoazines fused to imidazoles.

The traversal is also on the ground that no lack of unity was made in the international phase. This is not found persuasive because the United States Patent and Trademark Office is *not* bound by the lack of unity determination by another International Searching Authority. MPEP 1875 states that whether or not the question of unity of invention has been raised by the International Searching Authority, it may be considered by the examiner when serving as an authorized officer of the International

Preliminary Examining Authority. Thus, the Examiner is *not* bound by any previous determination made. In addition, 37 C.F.R. 1.484 indicates that the international preliminary examination is a non-binding opinion. Finally, 37 C.F.R. 1.499 states that, if the Examiner finds that a national stage application lacks unity of invention under 37 C.F.R. 1.475, the Examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Thus, the determination of lack of unity is proper under the PCT treaty.

In regard to the argument that Groups I –VIII do not cover all of the subject matter, the examiner disagrees with applicants. Note that Group VIII is drawn to others not to other forms as alleged by applicants. Others will include compounds that don't fall into Groups I-VII, such as metal complex, quaternary amine, N-oxide, any heterocyclic ring in b4, e.g Y1 = N and u =1-2 etc). Contrary to applicant's argument, the 6-8 membered carbocyclic rings are grouped with Q = non-heterocyclic ring.

Note that Group VIII is drawn to others, but not to other forms. Therefore, any Groups or combinations that don't fall in Groups I-VII, are drawn to said group. Thus, Group VIII should read as:

Group VIII, claim(s) 1-2 (in part), 8-15 (in part) and 18-21 (in part), drawn to others (such as quaternary amine, N-oxide, metal complex, heterocyclic ring in b4 e.g azetidine, etc.).

The requirement is still deemed proper and is therefore made FINAL.

3. During a telephone conversation with Ms. Wendy Choi on June 3, 2003, the examiner indicates that Q = non-heterocyclic ring will include b-1- b3, b-4 when Y1 is C, and b-5 and b-7 when Y1 is C.
4. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action.

#### ***Abstract***

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

#### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6, 8-15, and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a. Claim 1 and claims dependent thereon are rejected because the phrase "wherein =Z is =O, =CH-C(=O)-NR<sup>5a</sup>R<sup>5b</sup>, .." is not clear. What is the significance of the double bond in front of variable Z? Does applicants intend to claim ==O or just =O? If the latter is true, applicants have to delete the double bonds from the definition of variable Z. It is recommended that the claim reads "wherein Z is O, CH-C(=O)-NR<sup>5a</sup>R<sup>5b</sup>, CH<sub>2</sub>.." to overcome the rejection.
- b. Regarding claim 1 (page 6, lines 7 and line 28), the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
- c. In claim 10 the phrase "method of using as a medicine a compound" is indefinite. This is a mental step. If it is method claim, then it should be written as a method claim language.
- d. In claim 10, the term "medicine" is indefinite. Medicine for what?
- e. In claim 15 or elsewhere in the claims, the term "suitable" is indefinite. What is included and what is not? How can one tell what is suitable and what is not? It is recommended that applicants recite the actual reagents, instead of using "suitable reducing agent, suitable amination reagent...etc."

***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624

KH  
June 5, 2003



Mukund J. Shah  
Supervisory Patent Examiner  
Art Unit 1624